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117TH CONGRESS
2D SESSION

S. 4262

To temporarily allow the importation of infant formula free of duty and free of quantitative limitation, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 19 (legislative day, MAY 17), 2022

Mr. LEE introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To temporarily allow the importation of infant formula free of duty and free of quantitative limitation, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Formula Act of 2022''.

SEC. 2. INCREASING THE SUPPLY OF INFANT FORMULA.

(a) IN GENERAL.—During the 180 day period beginning on the date of the enactment of this Act, infant formula classified under heading 1901.10 of the Harmonized Tariff Schedule of the United States shall enter the

United States free of duty and free of quantitative limitation, if such formula—

(1) is imported from a country on the list published by the Secretary of Health and Human Services under subsection (c)(1) or a member country of the European Union; and

(2) is lawfully marketed in the country of origin.

(b) GUIDANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection and in subsection (c) as the ''Secretary'') shall, not later than 7 days after the date of enactment of this Act, issue, and periodically update, as appropriate, guidance for domestic and foreign manufacturers of infant formula in order to increase availability of such formula in the United States that is safe and nutritionally adequate.

(2) ELEMENTS OF THE GUIDANCE.—The guidance under paragraph (1) shall address the following:

(A) Information to be submitted to the Secretary by foreign and domestic manufacturers of infant formula for consideration with regard to the introduction into interstate com-

merce (including importation) of infant formula that is safe and nutritionally adequate but that may not comply with all applicable statutory and regulatory requirements. Such information shall include—

(i) safety and nutritional adequacy of the infant formula;

(ii) product identification information;

(iii) the quantity of the infant formula intended for introduction into interstate commerce;

(iv) a copy of the label for the infant formula (with information on any allergens present on the product label and adequate instructions for safe product preparation and use) and description of the packaging of the infant formula; and

(v) manufacturing information, including test results, and facility compliance and inspection history.

(B) Information for manufacturers planning to increase domestic production of infant formula for purposes of addressing the ongoing shortage.

(3) PRIORITY.—The guidance under paragraph (1) shall provide for priority consideration for manufacturers that are able to produce large volumes of such infant formula quickly.

(c) IMPORTATION FROM COUNTRIES MEETING CERTAIN STANDARDS.—

(1) IN GENERAL.—Not later than 7 days after the date of enactment of this Act, the Secretary shall publish a list of countries the Secretary determines to have manufacturing and safety standards for infant formula that are similar, equivalent, or otherwise suitable, as compared to United States standards.

(2) PERSONAL AND COMMERCIAL IMPORTATION.—Beginning on the date on which the list of countries is published under paragraph (1), for a period not to exceed 180 days, the Secretary shall allow personal and commercial importation of infant formula from any country on such list, as well as from any member country of the European Union, without regard to the guidance under subsection (b)(2) and the requirements of section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a), section 415 of such Act (21 U.S.C. 350d),

and parts 106 and 107 of title 21, Code of Federal Regulations.

(d) DEFINITION.—In this section, the term ''infant formula'' has the meaning given such term in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)).

SEC. 3. SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS, AND CHILDREN.

(a) ACCESS FOR WIC BENEFICIARIES.—Notwithstanding any other provision of law, any infant formula (as defined in section 2(d)) imported into the United States pursuant to section 2(c)(2) is eligible for purchase using benefits received under the special supplemental nutrition program for women, infants, and children established by section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786).

(b) PRODUCT RECALLS AND SUPPLY CHAIN DISRUPTIONS.—Section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786) is amended—

(1) in subsection (b), by adding at the end the following:

''(24) SUPPLY CHAIN DISRUPTION.—The term 'supply chain disruption' means a shortage of supplemental foods that impedes the redemption of food instruments, as determined by the Secretary.''; and

(2) by adding at the end the following:

''(r) PRODUCT RECALLS AND SUPPLY CHAIN DISRUPTIONS.—

''(1) DEFINITION OF QUALIFIED ADMINISTRATIVE REQUIREMENT.—In this subsection, the term 'qualified administrative requirement' means—

''(A) a requirement under this section; and

''(B) any regulatory requirement promulgated pursuant to this section.

''(2) MODIFICATION OR WAIVER OF REQUIREMENTS.—Notwithstanding any other provision of law, the Secretary shall modify or waive a qualified administrative requirement to allow 1 or more State agencies—

''(A) to permit vendors authorized to participate in the program under this section to exchange or substitute authorized supplemental foods obtained with food instruments with food items that are not identical (including in brand and size);

''(B) to modify or waive any requirement with respect to medical documentation for the issuance of noncontract brand infant formula, except the requirements for participants receiving Food Package III (as defined in section

246.10(e)(3) of title 7, Code of Federal Regulations (as in effect on the date of enactment of this subsection));

"(C) to modify or waive the maximum monthly allowance for infant formula;

"(D) to modify or waive any additional requirement with respect to supplemental food products provided under the program under this section if the modification or waiver—

"(i) may facilitate increased access to those products;

"(ii) does not substantially weaken the nutritional quality of those products; and

"(iii) is in accordance with any applicable guidance or directive from the Administrator of Food and Drugs determined to be applicable by the Secretary.

"(3) DURATION.—A modification or waiver under paragraph (2)—

"(A) shall be available for a period of not more than 180 days beginning on the date of enactment of this subsection; and

"(B) may be renewed, subject to the condition that the Secretary shall provide notice of

the renewal not less than 15 days before the renewal shall take effect.''.

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